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EXAMINER				
SUN, XIUQIN				
ART UNIT		PAPER NUMBER		
2863				
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06/18/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/783,675

Applicant(s)

SAY ET AL.

Examiner

XIUQUIN SUN

Art Unit

2863

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-142 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 41-142 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CIS)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Response to Amendment

1. Upon further consideration the Examiner presents the following election/restriction requirement to the amended claims received 03/07/2008. Any inconvenience to the Applicant(s) is regretted.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 41, 42, 47-53 and 54, drawn to computer systems for data collection and transmission, classified in class 702, subclass 19.
 - II. Claims 43-46 and 85-100, drawn to computer systems for data collection, transmission, calibration and evaluation, classified in class 702, subclasses 85.
 - III. Claims 55-84 and 101-142, drawn to a device and computer systems for monitoring glucose concentration, presenting monitored data and outputting results, classified in class 600, subclasses 365.
3. The inventions are distinct, each from the other because of the following reasons:
- Inventions I and II are related as combination (Invention I) and subcombination (Invention II). Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed

does not require the particulars of the subcombination as claimed because Invention I does not require a module for calibrating the sensed data. The subcombination Invention II has separate utility such as calibrating and evaluating the sensed data stream based on input reference data.

Inventions I and III are related as combination (Invention I) and subcombination (Invention III). Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because Invention I does not require a module for calibrating the sensed data and modules for presenting the data. The subcombination Invention III has separate utility such as calibrating the sensed data stream based on input reference data and outputting the results.

Inventions II and III are related as combination (Invention II) and subcombination (Invention III). Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because Invention II does not modules for presenting the data. The subcombination Invention III has separate utility such as calibrating the sensed data stream based on input reference data and outputting the results.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
5. If applicant elects invention II, applicant is further required to elect a single species from the following patentably distinct Species:

Species II.1, as best illustrated in claim 43.

Species II.2, as best illustrated in claim 44.

Species II.3, as best illustrated in claim 45.

Species II.4, as best illustrated in claim 46.

Species II.5, as best illustrated in claims 85-100.

6. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

For example the cited section contains mutually exclusive characteristics:

In claim 43, a computer system for processing analyte data, including a calibration module configured to form calibration information based at least in part on at least one reference data point and at least one sensor data point, wherein the reference data point and the sensor data point are obtained at substantially corresponding times,

and wherein the rate of change of the data stream is below a threshold at the time the sensor data point is obtained.

In claim 44, a computer system for processing analyte data, including a conversion function module configured to create a conversion function based at least in part on at least one sensor data point, wherein the sensor data point is obtained when the rate of change of the data stream is below a threshold, and wherein the conversion function is configured to convert the sensor data point into a calibrated data point.

In claim 45, a computer system for processing analyte data, including a sensor data transformation module configured to convert at least one sensor data point into a calibrated data point, wherein the rate of change of the data stream at the time at which the sensor data point is obtained is below a threshold.

In claim 46, a computer system for processing analyte data, including a calibration module configured to form a calibration set based at least in part on at least one matched data pair, the matched data pair comprising a reference data point and a sensor data point, wherein the reference data point and the sensor data point are obtained at substantially corresponding times.

In claims 85-100, a computer system suitable for processing analyte data, the computer system including a processor module configured to calibrate the data stream based at least in part on the at least one reference data point, wherein the processor module is further configured to determine a rate of change of the calibrated data stream, and wherein the processor module is further configured not to calibrate the data stream

using reference data obtained during a time when the rate of change of the calibrated data stream is above a threshold.

7. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 85-100 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

8. If applicant elects invention III, applicant is further required to elect a single species from the following patentably distinct Species:

Species III.1, as best illustrated in claims 55-84.

Species III.2, as best illustrated in claims 101-121.

Species III.3, as best illustrated in claims 122-142.

9. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

For example the cited section contain mutually exclusive characteristics,

In claims 55-84, a device for monitoring glucose concentration in a biological sample of a host, the device a single point glucose monitor configured to receive a biological sample from the host and to measure the concentration of glucose in the

sample, the measured glucose concentration comprising a reference data point; a processor; and a computer readable memory including instructions configured to cause the processor to process the data stream received from the continuous glucose sensor; instructions configured to cause the processor to determine a rate of change of the data stream from the substantially continuous analyte sensor; and instructions configured to cause the processor to calibrate the data stream using the glucose concentration measured by the single point glucose monitor.

In claims 101-121, a computer system suitable for processing analyte data, the computer system including a processor module configured to calculate a rate of change value associated with a rate of change of the analyte concentration, and wherein the processor module is further configured to substantially continuously display, on a user interface, a directional arrow representative of the calculated rate of change value.

In claims 122-142, a computer system suitable for processing analyte data, the computer system including a processor module configured to determine a rate of change of the data stream, and wherein the processor module is further configured to simultaneously display, on a user interface, a numeric analyte concentration, an indication of rate of change of analyte concentration, and a graphical representation of analyte concentration over a period of time.

10. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 101-142 withdrawn from consideration

as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

11. If applicant elects invention III.1, applicant is further required to elect a single species from the following patentably distinct Species:

Species III.1.1, as best illustrated in claims 55-69 and 73.

Species III.1.2, as best illustrated in claims 55, 70-71 and 74-78.

Species III.1.3, as best illustrated in claims 55 and 72.

Species III.1.4, as best illustrated in claims 55 and 80.

Species III.1.5, as best illustrated in claims 55 and 81.

Species III.1.6, as best illustrated in claims 55 and 82.

Species III.1.7, as best illustrated in claims 55 and 83.

Species III.1.8, as best illustrated in claims 55 and 84.

12. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 55 is generic.

For example the cited section contain mutually exclusive characteristics:

In claims 55-69 and 73, a device for monitoring glucose concentration in a biological sample of a host, the device including the anatype including glucose, wherein the data stream comprises measurements indicative of in vivo glucose concentration,

and wherein the threshold is 0.25 mg/dL/min, and wherein the threshold is 0.5/greater than 0.5 mg/dL/min.

In claims 55, 70-71 and 74-79, a device for monitoring glucose concentration in a biological sample of a host, the device including instructions configured to cause the processor to receive user information from an external source and process the user information received from the external source, information selected from the group consisting of mealtime information, exercise information, insulin administration, therapy recommendations and reference analyte values.

In claims 55 and 72, a device for monitoring glucose concentration in a biological sample of a host, the device including instructions configured to detect at least one of present hypoglycemia, predicted hypoglycemia, present hyperglycemia and predicted hypoglycemia, wherein the instructions are configured to trigger an alarm or alert in response to the detection.

In claims 55 and 80, a device for monitoring glucose concentration in a biological sample of a host, the device including instructions configured to receive and process software updates from an external source.

In claims 55 and 81, a device for monitoring glucose concentration in a biological sample of a host, the device including the integrated receiver is adapted to fit on a belt.

In claims 55 and 82, a device for monitoring glucose concentration in a biological sample of a host, the device including the integrated receiver is the size of a pager.

In claims 55 and 83, a device for monitoring glucose concentration in a biological sample of a host, the device including the integrated receiver is bedside unit.

In claims 55 and 84, a device for monitoring glucose concentration in a biological sample of a host, the device including the integrated receiver including a cell phone.

13. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 70-72 and 74-84 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

14. Species are always the specifically different embodiments. Species (maybe either) independent or related as disclosed (See MPEP 806.04(e) and 806.04(b)) Note: in this case, the species are best illustrated using claims, MPEP 809.02(a) [R-3]). It is noted that numerous additional embodiments have been disclosed in the specification. Should Applicant introduce claims directed to additional species or amend the claims to be directed toward species distinct from the elected species, the claims may be subject to further restriction. (See 37 CFR 1.142(b) and MPEP § 821.03.)

15. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

16. The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election Without traverse. Traversal must be presented at the time of election in order to be considered timely, Failure to timely traverse the

requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

17. If a response to a restriction requirement includes an election with traverse on the grounds that the groups are not patentably distinct, applicant must present evidence or identify such evidence of record showing the groups to be obvious variations of one another. Traversal of a restriction requirement alone without an explanation in support thereof will be treated as an election without traverse. See MPEP § 818.03(a) and form paragraph 8.25.02.

18. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.
MPEP § 809.02(a)

19. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

20. In accordance with MPEP 812.01, as revised July 1996, because of the complexity of issues involved in the following election of species, no telephone call was made to the Applicant to receive an election.

Contact Information

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiuqin Sun whose telephone number is (571)272-2280. The examiner can normally be reached on 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Barlow can be reached on (571)272-2269. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit: 2863

/X. S./

Examiner, Art Unit 2863

/Tung S. Lau/

Tung S. Lau, Art Unit 2863

Primary Examiner

June 12, 2008